

REMARKS

I. Status of the Claims

Claims 1-23 and 28-38 are pending, with claims 30-38 being newly added by this Amendment. Claim 9 is withdrawn, and claims 1, 22, 23, 28, and 29 have been amended to delete an extra period appearing in formula VII.

Claim 3 is allegedly withdrawn. "Claims 3 and 9 are withdrawn from consideration, as they are directed to non-elected subject matter." Office Action at page 2. It cannot be seen where claim 3 was restricted from the examined claims. In fact, only claim 9 finds mention as being withdrawn in recent Office Actions. See, e.g., Office Action dated May 3, 2002, at page 2. Applicants respectfully disagree that claim 3 should be withdrawn, and respectfully request that claims 3 and 9 be rejoined and examined.

New claim 30 recites, "A method of treating skin substantially without hair cover." Support for this language can be found, among other places, in the specification at page 18, line 9 to page 19, line 14. New claims 31-33 correspond to original claims 2-4, respectively; claim 34 corresponds to original claim 11; and claims 35-38 correspond to original claims 18-21, respectively. Additional support for these new claims can be found throughout the application as originally filed.

II. "Response to Arguments"

The Examiner alleges that "Applicant has provided no arguments," referring to the Preliminary Amendment filed on November 1, 2002. Office Action at page 2.

Applicants respectfully disagree, and point to pages 17-19 of that Preliminary

Amendment. There, it was explained how the alleged prior art does not teach or suggest Applicants' claimed invention. If the Examiner has not done so, Applicants respectfully request that the entire filing dated November 1, 2002, be fully considered as required by M.P.E.P. § 707.07(f) (stating "the examiner should . . . take note of the applicant's argument and answer the substance of it.").

III. Continued Prosecution Application under 37 C.F.R. § 1.53(d)

The Examiner states that "[a] request for continued examination [RCE] under 37 C.F.R. 1.114 . . . was filed in this application after final rejection." Office Action at page 2. However, Applicants filed a Continued Prosecution Application ("CPA") under 37 C.F.R. § 1.53(d) on November 1, 2002. Applicants respectfully request that the present application be treated as a CPA in accordance with their filing.

IV. Election and Restriction Requirements

The Examiner maintains the election and restriction requirements first made in the Office Action dated November 15, 2000. Office Action at page 2. Applicants confirm their elections of record, which were made with traverse. See Office Action dated November 15, 2000 at page 3; Amendment and Response filed April 9, 2001 at pages 3-6. Applicants maintain their traverses, and respectfully request the Examiner to rejoin and examine a reasonable number of species with the elected species should the elected species be found patentable. It would be unreasonable, for example, to require Applicants to file a separate application for each of "at least one physiologically tolerated solvent."

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V. Claim Rejection under 35 U.S.C. § 112, ¶ 1

Claim 10 has been rejected under 35 U.S.C. § 112, ¶ 2, for allegedly being indefinite. Office Action at pages 2-3. The Examiner questions whether “acrylate copolymers” and “acrylic acid ester copolymers” are synonymous. Also, the Examiner questions whether the claim recites a range within a range. *Id.* at page 3. Applicants respectfully traverse this rejection.

Applicants point out that “acrylate copolymers” are not synonymous with “acrylic acid ester copolymers.” The “ester” requires a substituent, usually an alkyl, to be bonded to an oxygen atom of the acrylic acid moiety. The “acrylate,” on the other hand, does not require an “ester” substituent on the oxygen atom, and so the terms cannot be synonymous.

Also, the claim does not recite an improper “range within a range.” The Examiner’s allegation is more akin to an assertion that the claim recites a Markush group comprising a genus and a subgenus within that genus. For sake of argument, it might be said that “acrylic acid ester copolymers” states a genus, and “ethylene/acrylic acid ester copolymers” states a subgenus within that genus. This alleged “double inclusion” is perfectly acceptable, so long as this does not render the claim indefinite or result in undue multiplicity. See M.P.E.P. § 2173.05(h). That section of the M.P.E.P. illustrates: “For example, the Markush group, ‘selected from the group consisting of amino, halogen, nitro, chloro, and alkyl’ should be acceptable even though ‘halogen’ is generic to ‘chloro.’ ” *Id.*

This rejection, therefore, should be withdrawn.

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VI. Claim Rejections under 35 U.S.C. § 103

A. *Cretois* in view of *Dubois*

Claims 1-2, 4-8, 10-13, 16-17, 22-23, and 28-29 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Cretois* (U.S. Patent No. 5,558,859) in view of *Dubois* (U.S. Patent No. 6,162,444). Office Action at pages 3-5. The Examiner acknowledged that *Cretois* "lacks instant formula (I) and 5-alpha-reductase inhibitors," and cited *Dubois* to overcome these deficiencies. Office Action at page 4. Applicants respectfully disagree with this rejection.

As an initial matter, the claimed invention should be examined as a whole. In the Office Action at page 5, the Examiner has alleged that the claim language "wherein said compound of formula I is released from the film formed by application of said composition to a skin surface" is merely a property of the composition and its constituents, and so this language is given no weight. On the contrary, this claim language excludes those compositions that fail to release the compound, and so distinguishes the claimed subject matter. See specification at page 3, line 25 to page 4, line 5; and page 4, lines 12-21. "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' " M.P.E.P. § 2111 (*citing In re Hyatt*, 211 F.3d 1367, 1372, 54 U.S.P.Q.2d (BNA) 1664, 1667 (Fed. Cir. 2000)). The broadest reasonable interpretation of this language could not reach a composition having the same ingredients but formulated so that the compound of formula I is withheld from the skin surface, for example. Accordingly, this claim language should be given weight.

Applicants respectfully contend that a *prima facie* case has not been made. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. M.P.E.P. § 2143.

The combination proposed by the Examiner lacks the requisite motivation to combine, because *Cretois* and *Dubois* treat different parts of the body. *Cretois* teaches hair, eyelash, and nail compositions, and exemplifies hair styling mousses and mascaras. See *Cretois* at cols. 7-9. In contrast, *Dubois* teaches skin compositions useful for treating cancers and skin afflictions. See *Dubois* at col. 6, lines 49-59. One of ordinary skill in the art would not combine a hair treatment with a skin treatment without significant hindsight reasoning.

To support the combination of *Cretois* and *Dubois*, the Examiner has mischaracterized the teaching of *Cretois*. "*Cretois* teaches compositions for the treatment and protection of the exoskeletal parts, such as hair and skin." Office Action at page 3 (emphasis added). *Cretois*, however, does not mention skin. To *Cretois*, "Exoskeletal parts include the hair, the eyelashes, the eyebrows, the fingernails or the toenails." *Cretois* at col. 2, lines 6-8. Furthermore, *Cretois* describes a "hair styling mousse" in Example 1, another "hair styling mousse" in Example 2, a "hair-setting lotion" in Example 3, and a "mascara" in Example 4. *Id.* at cols. 7-9. *Cretois* does not disclose a "skin composition."

On the other hand, Dubois teaches skin compositions. "The topical use of an active ingredient encapsulated in liposomes allows the active ingredient to be concentrated in the sebaceous glands to obtain a higher and longer-lasting concentration in the epidermis and in the dermis in vivo." *Dubois* at col. 4, lines 42-45. Further, "According to the invention, the liposomes containing the active ingredient localize the penetration into the epidermis and into the sebaceous glands while minimizing passage into the circulatory system." *Id.* at col. 6, lines 45-58. The skilled artisan reading this would not find motivation to combine *Dubois'* teaching with, say, a "hair styling mousse."

For these reasons, Applicants contend that *Cretois* and *Dubois* teach compositions useful for different purposes, *Cretois* teaches hair and nail compositions, and *Dubois* teaches skin compositions. Therefore, a skilled artisan would not find the motivation or reasonable expectation of success in the proposed combination of these two references. Nonetheless, the Examiner enlarged the subject areas of the two references until a common purpose could be stated: "Dubois and Cretois are both directed to topical cosmetic compositions." Office Action at page 4. However, it is not enough even to find that alleged prior art compositions are directed to the same purpose.

A much closer rejection was reversed by the Federal Circuit in *In re Geiger*, 815 F.2d 686, 2 U.S.P.Q.2d (BNA) 1276 (Fed. Cir. 1987). The *Geiger* applicants claimed a method of inhibiting scale formation and corrosion in a cooling water system using a composition comprising three ingredients. The references individually taught combinations of perhaps two of applicants' three ingredients in compositions for

preventing scale in boiling or cooling water systems, with all three ingredients being disclosed by several references.

Yet the Federal Circuit found no suggestion to combine all three ingredients in one composition for the purpose of inhibiting scaling and corrosion in a cooling water system. It was not enough that the three ingredients appeared in the prior art, even in compositions useful for the same purpose as applicants' claimed method. The court rejected the PTO's finding of a *prima facie* case of obviousness, stating, "At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, this is not the standard of 35 U.S.C. § 103." *In re Geiger*, 815 F.2d at 688, 2 U.S.P.Q.2d at 1278.

In the present case, *Cretois* and *Dubois* are not even directed to compositions disclosed for the same purpose. If the rejection in *Geiger* was reversed, then the present rejection should be withdrawn.

B. *Cretois* in view of *Dubois* in further view of Additional References

Claims 14, 15, and 19-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over *Cretois* in view of *Dubois*, in further view of additional references. These additional documents are *Lai* (U.S. Patent No. 5,916,910) (for claim 14); *Ismail* (U.S. Patent No. 5,541,220) (for claim 15); *WO '317* (WO 92/21317) (for claim 19); and *WO '701* (WO 91/19701) (for claims 20-21). Office Action at pages 5-7. Applicants respectfully disagree with these rejections.

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Each of these rejected claims depend ultimately from claim 1, and so incorporate by reference all the limitations of claim 1. See 35 U.S.C. § 112, ¶ 4. Claim 1 requires a compound of formula (I), among other things. As discussed above, the Examiner has not shown the requisite motivation to combine *Dubois* with *Cretois*, so the proposed combinations lack the motivation to include the compound of formula (I). Thus, each of these additional rejections should be withdrawn.

VII. Comment on New Claims 30-38

New claims 30-38 relate to methods for treating "skin substantially without hair cover." These claims are patentable over the cited documents, at least because *Cretois* does not teach or suggest treating skin substantially without hair cover.

CONCLUSION

Applicants respectfully request reconsideration and reexamination of the pending claims.

A Petition for Extension (Two Months) accompanies this Amendment, along with a check for the extension fee. Please grant any additional extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,
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By: 
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